

## **REMARKS**

Claim 19 has been amended. Claims 1-19 are pending in the application. Entry of the amendment, and reexamination and reconsideration of the application based on the above-indicated amendments and the following remarks are respectfully requested.

The Examiner's finding that claims 1-14 and 17 are allowed is acknowledged with thanks.

Claims 15, 18 and 19 have been rejected under 35 U.S.C. § 112, second paragraph, for the reasons indicated on page 2 of the office action. These rejections are respectfully traversed or are believed to have been obviated for the following reasons:

Claim 15 and 18 were previously amended to specify the use of the terms "dissoluble solvent" and "indissoluble solvent." These terms are consistent with the terminology used in the specification; see, for example, page 9, lines 2-23. The Applicant's claimed method, as specified in claims 15 and 18, relates to an anti-solvent solidification process wherein the compound (I) or solvate is dissolved in a "dissoluble solvent," and then a "indissoluble solvent" is added to precipitate a crystal. See, Applicant's specification at page 10, lines 6-13. The term "dissoluble solvent" refers to a solvent used to dissolve the compound (I) or solvate. The term "indissoluble solvent" refers to a solvent used to precipitate crystal from the solution containing the compound (I) or solvate. The terms "dissoluble solvent" and "indissoluble solvent" as used herein would be readily understood by those skilled in the art.

Claim 19 has been amended in line 2 by changing the term "1-hydrate" to "monohydrate." This correction is being made to overcome an obvious translation error.

Applicant respectfully submits that claims 15, 18 and 19 are in compliance with 35 U.S.C. § 112, second paragraph. Withdrawal of the rejection is requested.

Applicant respectfully submits that this application is in condition for allowance. A Notice of Allowance is respectfully solicited.

In the event there are any issues the Examiner would like to discuss with the undersigned attorney, it is requested that he contact the undersigned by telephone.

In the event any fees are due in connection with the filing of this document, the Commissioner is authorized to charge those fees to our Deposit Account No. 18-0988 under Attorney Docket No. SHIOP0100US.

Respectfully submitted,

RENNER, OTTO, BOISSELLE & SKLAR, LLP

By:   
Neil A. DuChes, Reg. No. 26,725

1621 Euclid Avenue - 19<sup>th</sup> Floor  
Cleveland, Ohio 44115-2191  
(216) 621-1113